

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref: Customs Entry No. WAM-0120294-2
Product: Fresh Big-Eye Tuna

WARNING LETTER

FLA-98-44

April 6, 1998

Mr. Jaime Yuken
Manager
Fleishman's Seafood Handling, Inc.
1177 N.W. 81st Street
Miami, Florida 33150

Dear Mr. Yuken:

The Food and Drug Administration (FDA) requested to examine a shipment of fresh big-eye tuna offered for entry into the United States by your firm on March 16, 1998, under the above referenced entry number, and determined that the shipment was not available for FDA examination. The original entry consisted of 43 cases of fresh big-eye tuna. Our inspector collected a sample from the 29 cases, which were held for FDA examination. Fourteen (14) cases were distributed without an FDA "May Proceed" or a "Notice of Release". Regulation 1.90, Title 21, Code of Federal Regulations, (21 CFR 1.90) requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. We requested the U. S. Customs Service (Customs) to order redelivery on 14 cases of this shipment (copies enclosed).

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of future shipments. It is your responsibility, as the importer, to ensure that imported products meet all the requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

We request a response in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the recurrence of the violation.

Jaime Yuken
Page 2
April 6, 1998

Your written reply should be addressed to the Food and Drug Administration, Attention:
Paul R. Bagdikian, Compliance Officer, P. O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,

A handwritten signature in black ink, appearing to read "Douglas D. Tolen". The signature is fluid and cursive, with a long horizontal stroke extending to the left.

Douglas D. Tolen
Director, Florida District

Enclosure

cc: District Director
U. S. Customs Service
P. O. Box 52-3215
Miami, Florida 33152-3215

Townsend Logistics, Inc.
1177 N.W. 81st Street
Miami, Florida 33150